K020049

510(K) SUMMARY

MAR 1 8 2002

Submitted by:
Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Contact
Patrick R. Bilbo
Telephone: (781) 401-1155
Facsimile: (781) 401-1109

Date: January 4, 2002

Device:

Trade Name:	FortaFlex™ Surgical Mesh
Common/Usual Name:	Surgical Mesh, Tissue Repair Biomaterial
Classification Name:	Surgical Mesh (79FTM, 878.3300)
Regulatory Class:	Class II

Predicate Device:
The FortaFlex Surgical Mesh is equivalent to the material cleared in K011025 for use in surgical procedures for reinforcement of soft tissue. The relevant predicate device for the expanded indications for use is the Restore® Orthobiologic Soft Tissue Implant (K001738) manufactured by DePuy, Inc.

Statement of Substantial Equivalence:
The FortaFlex Surgical Mesh is substantially equivalent to the predicate device, having similar intended use, technological characteristics, materials, physical construction and performance.

Intended Use:
FortaFlex™ Surgical Mesh is intended to be used for implantation to reinforce soft tissue including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement and reconstructive procedures. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery. The device is intended for one-time use.

Device Description:
FortaFlex Surgical Mesh consists of a multi-laminate sheet predominantly of Type I porcine collagen. The device is supplied in sheet form in sizes ranging from 5 x 5 cm to 12 x 36 cm in sterile double layer peelable packaging.

Performance Data:
FortaFlex Surgical Mesh was subjected to a panel of tests to assess biocompatibility, integrity, and performance. The device passed the requirements of all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2002

Mr. Patrick R. Bilbo
Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Re: K020049
Trade/Device Name: FortaFlex™Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: January 4, 2002
Received: January 7, 2002

Dear Mr. Bilbo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Organogenesis Inc.

510(k) Number (if known): K020049

Device Name: FortaFlex™ Surgical Mesh

Indications For Use:

FortaFlex™ Surgical Mesh is intended to be used for implantation to reinforce soft tissue including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement and reconstructive procedures.

The device is also intended for reinforcement of the soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.

The device is intended for one-time use.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020049

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)